Saskatchewan Ministry of Health

Drug Plan and Extended Benefits Branch

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SASKATCHEWAN FORMULARY BULLETIN
UPDATE TO THE
59th EDITION OF THE
SASKATCHEWAN FORMULARY

The following listings are effective **July 1, 2009**, unless otherwise indicated.

NEW FULL FORMULARY LISTINGS:

- Ethinyl estradiol/drospirenone, tablet, 0.020mg/3.0mg (28 tablet) (YAZ-BAY)
- Fenofibrate, tablet, 48mg, 145mg (Lipidil EZ-SLV)

NEW EXCEPTION DRUG STATUS LISTINGS EFFECTIVE JULY 1, 2009:

- Duloxetine hydrochloride, delayed release capsule, 30mg, 60mg (Cymbalta-LIL)

a) For the treatment of neuropathic pain in diabetic patients unresponsive following treatment with adequate doses of tricyclic antidepressants (TCA) as indicated on the patient profile by 2 consecutive prescriptions for a TCA within 6 months of the EDS request, or
b) For the treatment of neuropathic pain in diabetic patients intolerant or contraindicated to tricyclic antidepressants.
Coverage will be provided to a maximum daily dose of 60mg.

- Fosamprenavir calcium, oral suspension, 50mg/mL (Telzir-GSK)

For coverage according to the current criteria for fosamprenavir calcium.

- Insulin detemir, injection solution, 100U/mL (5x3mL) (Levemir-NOO)

For the treatment of patients who have been diagnosed with Type 1 or Type 2 diabetes requiring insulin and are currently taking insulin NPH and/or pre-mix daily at optimal dosing **AND**
a) Have experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management
OR
b) Have documented severe or continuing systemic or local allergic reaction to existing insulin.

- Natalizumab, solution for IV infusion, 20mg/mL (Tysabri-BGN)

For monotherapy treatment in patients with a diagnosis of multiple sclerosis who also meet **ALL** of the following criteria:
a) Failure to respond to full and adequate courses of treatment with at least two disease-modifying therapies or have contraindications to, or be intolerant of these therapies, **AND**
b) Significant increase in T2 lesion load compared to a previous MRI or at least one gadolinium-enhancing lesion, **AND**
c) Two or more disabling relapses in the previous year.

- Pantoprazole magnesium, enteric-coated tablet, 40mg (Tecta-NYC)

a) For a maximum of 8 weeks in treatment of peptic ulcer disease, which includes gastric and duodenal ulcers, in patients not responding or experiencing unusual or severe adverse reactions to a reasonable trial with H_2 blockers, sucralfate or misoprostol. *Coverage for a repeat treatment will be approved only after a 3-6 months period of no treatment or prophylaxis with an H_2 blocker, sucralfate or misoprostol.*
b) For treatment of symptoms of gastroesophageal reflux disease (GERD). *It was noted that patients with non-erosive GERD could potentially be reduced to step-down therapy with an H_2 antagonist depending on symptom resolution.*
c) For treatment of severe erosive esophagitis and Zollinger-Ellison Syndrome.
d) For one week for eradication of H. pylori-related infections in individuals with peptic ulcer disease. *Provision will be made for additional coverage in treatment failures.*
e) For first-line prevention of gastroduodenal hemorrhage in high risk patients with prior history of gastroduodenal bleeds for whom anticoagulant, glucocorticosteroid or NSAID therapy cannot be avoided. *Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible.*
f) For a maximum of 8 weeks in patients discharged from hospital, on a proton pump inhibitor, following a gastroduodenal bleed.

- Pregabalin, capsule, 25mg, 50mg, 75mg, 150mg, 300mg (Lyrica-PFI)

a) For the treatment of neuropathic pain in patients unresponsive following treatment with adequate doses of tricyclic antidepressants (TCA) as indicated on the patient profile by 2 consecutive prescriptions for a TCA within 6 months of the EDS request, or
b) For the treatment of neuropathic pain in patients intolerant or contraindicated to tricyclic antidepressants.

REVISED EXCEPTION DRUG STATUS CRITERIA:

- Botulinum toxin type A, sterile lyophilized powder, 100IU (Botox-ALL)

For treatment of:
a) Eye dystonias, that is, blepharospasm and strabismus.
b) Cervical dystonia, that is, torticollis.
c) Other forms of severe spasticity.
d) Hyperhidrosis of the axilla.
e) Children with non-neurogenic functional outflow obstruction due to external sphincter over-activity who are not candidates for or who have not responded to other options.
f) Spinal cord injury patients with chronic urinary retention who are not candidates for or who have not responded to other options.
Note: This criteria does not apply to patients with multiple sclerosis.

- Insulin aspart, injection solution, 100U/mL (5x3mL) (10mL) (NovoRapid-NOO)

a) For treatment of Type 1 diabetes.
b) For treatment of difficult to control Type 2 diabetes in patients who have not responded to alternative insulin agents listed in the Formulary.

- Insulin glulisine, solution for injection, 100U/mL (10mL); 100U/mL, pre-filled pen SoloSTAR (3mL) (Apidra-AVT)

a) For treatment of Type 1 diabetes.
b) For treatment of difficult to control Type 2 diabetes in patients who have not responded to alternative insulin agents listed in the Formulary.

- Insulin lispro, injection solution, 100U/mL (5x3mL) (10mL) (Humalog-LIL)

a) For treatment of Type 1 diabetes.
b) For treatment of difficult to control Type 2 diabetes in patients who have not responded to alternative insulin agents listed in the Formulary.

- Tiotropium bromide monohydrate, powder capsule, 18ug/dose (Spiriva-BOE)

a) For treatment of COPD in patients unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators, or
b) For treatment of moderate to severe COPD (i.e. Medical Research Council {MRC} dyspnea scale score 3 to 5) in conjunction with spirometry demonstrating moderate to severe airflow obstruction (i.e. FEV1 <60% and low FEV1/FVC <0.7), without a trial of short-acting agents.

A copy of the MRC dyspnea scale is shown below.

NEW INTERCHANGEABLE FULL FORMULARY OR EDS LISTINGS EFFECTIVE JUNE 1, 2009:

- Cilazapril/HCTZ, tablet, 5mg/12,5mg (Novo-Cilazapril/HCTZ-NOP)
- Ethinyl estradiol/desogestrel, tablet, 0.03mg/0.15mg (21 tablet) (28 tablet) (Apri-APX)
- Fentanyl, transdermal system, 25ug/hr, 50ug/hr, 75ug/hr, 100ug/hr (Novo-Fentanyl-NOP)
- Medroxyprogesterone acetate, injection suspension, 150mg/mL (1mL) (Medroxyprogesterone Acetate-SDZ)
- Methylphenidate HCl, sustained release tablet, 20mg (Sandoz Methylphenidate SR-SDZ)
- Omeprazole, capsule, 20mg (pms-Omeprazole DR-PMS)
- Pramipexole dihydrochloride, tablet, 0.25mg, 0.5mg, 1mg, 1.5mg (CO Pramipexole-COB)
- Raloxifene HCl, tablet, 60mg (Apo-Raloxifene-APX)
- Thiamine HCl, tablet, 50mg, 100mg (Jamp-Vitamin B1-JPC)

NEW INTERCHANGEABLE FULL FORMULARY OR EDS LISTINGS EFFECTIVE JULY 1, 2009:

- Enalapril maleate, tablet, 2.5mg, 5mg, 10mg, 20mg (Sig-Enalapril-SLI)
- Etidronate disodium/calcium carbonate, 400mg/1250mg tablet (pkg) (Novo-Etidronatecal-NOP)
- Ibuprofen, tablet, 400mg (Ibuprofen-JPC)
- Lansoprazole, delayed release capsule, 15mg, 30mg (Apo-Lansoprazole-APX)
- Levodopa/carbidopa, controlled release tablet, 100mg/25mg (Apo-Levocarb CR-APX)
- Levofloxacin, tablet, 250mg, 500mg (Novo-Levofloxacin-NOP) (pms-Levofloxacin-PMS); 750mg (pms-Levofloxacin-PMS)
- Pioglitazone HCl, tablet, 15mg, 30mg, 45mg (Accel Pioglitazone-ACC)

FROM THE ADVISORY COMMITTEE ON INSTITUTIONAL PHARMACY PRACTICE (ACIPP)

- Enoxaparin sodium, syringe, 30mg/mL, 40mg/mL, 60mg/mL, 80mg/mL, 100mg/mL (Lovenox-AVT)

Subject to the restricted criteria published in the Hospital Benefit Drug List in the Saskatchewan Formulary.
Note: the brand name will not appear in the HBDL as only generic names are published in this list.

- Rivaroxaban, tablet, 10mg (Xarelto-BAY)

According to the same criteria as published in Appendix A of the 59th Edition of the Saskatchewan Formulary.

Medical Research Council Dyspnea Scale

Grade	Degree of breathlessness related to activities
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying or walking up a slight hill
3	Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace
4	Stops for breath after walking about 100m or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing or undressing

Reference: Fletcher C.M. et al. 1959. The significance of respiratory symptoms and the diagnosis of chronic bronchitis in a working population. Brit. Med. J. 2:257–66.

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